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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/710,227
Filing Date: November 10, 2000
Appellant(s): GOURLEY, EWING B.

Benjamin L. Volk, Jr., Reg. No. 48,017
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/14/08 appealing from the Office action mailed 7/28/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

NEW GROUND(S) OF REJECTION

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

- Claims 1, 16-19, 20-29, 62-66 ,68, 76-77,78,79-80 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

6,003,006	Colella et al	12-1999
5,890,129	Spurgeon	04-1999

Gardner, Jerome Richard, "Pharmaceutical Scam: Use Audit to Detect 'Pyramid Cube Scheme'" , Healthcare Financial Management (HFM), vol. 36, no. 9 (Sept. 1982), pages 72, 74.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1, 16-19, 20-29, 62-66 ,68, 76-77,78,79-80 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a §101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr,*

450 U.S. 175, 184 (1981); *Parker* v. *Flook,* 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson,* 409 U.S. *63,* 70 (1972); *Cochrane* v. *Deener,* 94 U.S. 780,787-88 (1876). If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and should be rejected as being directed to nonstatutory subject matter.

Regarding claims 1, 16-19, 20-29, 76-77,and ,79-80, the current claim language does not include a required tie or transformation of subject matter. For example, the recited steps of claim 1,16, and 76 do not incorporate statutory subject matter and may be performed using mental processes (i.e. receiving an oral report and making mental decisions regarding the received information). The respective dependent claims provide details regarding the type of information received, but fail to include a tie to statutory subject matter or a transformation of subject matter into a different state or thing. Therefore, in providing an application of the above test to the current claims, a conclusion of nonstatutory subject matter is reached.

With respect to claims 62-66 ,68, and 78, although the preamble recites that the method is "computer-implemented," the claim language (i.e. the body of the claim) does also not include the required tie or transformation of subject matter. The recitation of "structure" is nominal and does not make exemplary claim 62 statutory, as it does not tie the structure to any of the process steps or to the transformation of any subject matter during or as a result of the recited method. As such, claims 62-66 ,68, and 78 are deemed to be nonstatutory subject matter.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 69 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a claim covering every conceivable means for achieving the recited purpose.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In particular, the claim recites "[a] system for determining whether a buyer qualifies for an "own use discount" comprising: a computer configured to perform an "own use" discount audit to determine whether an order qualifies for an "own use" discount." (A system comprising one component, which performs all functions, i.e. a single means claim.) The current claim does not expressly recite "means for" language. However, in *Fiers v. Revel,* (CAFC) 25 USPQ2d 1601, 1606 (1/19/1993), the CAFC affirmed a rejection under 35 USC 112 of a claim reciting a single element that did not literally use "means-plus-function" language.

Instant claim 69 is drawn to any "computer", regardless of construct, that performs the function recited. This parallels the fact situation in *Fiers* wherein "a DNA" and a result was recited. The CAFC stated in *Fiers* at 1606 "Claiming all DNA's that

achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived". See also *Ex parte Maizel,* (BdPatApp&Int) 27 USPQ2d 1662, 1665 and *Ex parte Kung,* (BdPatApp&Int) 17 USPQ2d 1545, 1547 (1/30/1989) where the claims at issue were rejected for being analogous to single *means* claims even though "means" was not literally used.

The Examiner notes the Applicant's arguments against the comparison of the current claim language that in the *Fiers* case. However, it is respectfully submitted that the recitation of a "computer" does not clarify which component(s) are present (i.e. the processor, the memory, input and output, and/or software). In other words, the claim language recites a system "that achieve[s] a result without defining what means will do so…" As such, the rejection of claim 69 is maintained.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 37, 43-44, and 69-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 currently recites the phrase: "depending upon whether said…comparison results in a sufficient number of matches between said audit data…and said order data."

The term "sufficient" in claim 37 is a relative term, which renders the claim indefinite. The term "sufficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For the purpose of applying art, the examiner will interpret this limitation to mean that there is a verification to determine whether quantities consistent with the patients' level of consumption (e.g. prescription) are performed.

A similar analysis may be applied to claims 43-44.

Claims 69-74

Claims 69-74 recite the limitation "a computer," "a second computer," and have been amended to recite "said computer." (See esp. claim 70) It remains unclear how many computers are present, and which computer is referenced by the phrase "said computer" and "the computer."

Claim describe 70 recites a second computer "in communication with *said computer* via a network.....wherein *the computer* is further configured to perform said "own use" audit…"

The claim limitations or recitations, particularly of claim in claim 70, render the functions of the computer in claim 69 unclear. In particular, it is unclear whether the single computer recited in claim 69 is now meant to perform all the functions of the "the

computer" or "said computer" or if "the computer"/ "said computer" refers to the second computer.

Claims 70-74 inherit the deficiencies of claim 69 through dependency and are also rejected.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 1, 9-10, 12-13,15-23,25,27-30,32-37,45-49, 62-66, and 68-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colella et al (USPN 6,003,006) in view of Gardner ("Pharmaceutical Scam: Use Audit to Detect 'Pyramid Cube Scheme'")

[claim 1] Colella discloses a method for processing orders for pharmaceuticals, said method comprising the steps of:

- receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical (Figs. 4, 6; col. 5, lines 33-43), wherein the said buyer includes an entity comprised of at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical. (col. 3, line 29-col. 4, line 26; col. 5, lines 33-43; Figure 1A) (Examiner interprets language to mean only one of the listed

options need to be included)

- receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; (col. 4, lines 1-9)
- comparing said order with said associated report to determine whether said associated report supports the order; and (col. 4, lines 17-44)

Colella teaches a method of processing “own use” prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize “own use” pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for “own use” discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 9] Colella discloses the method of claim 1 further comprising the step of entering said order as data into a computer. (col. 5, lines 33-43; Fig. 4, 6)

[claim 10] Colella teaches the method of claim 9 wherein the step of receiving said

associated report further comprises receiving said report as at least one computer file (i.e. in computer readable format), and wherein the comparison step is performed by a software program executed (col. 3, lines 29-39) on said computer (col. 4, lines 1-9; 17-44; 48-51)

[claim 12] Colella teaches the method of claim 9 further comprising the step of entering said associated report as data into said computer, (col. 4, lines 1-9), and wherein the comparison step is performed by a software program executed (col. 3, lines 29-39) on said computer (col. 4, lines 1-9; 17-44; 48-51)

[claim 13] Colella discloses the method of claim 9 further comprising the steps of:

- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer, said second associated report being received as at least one computer file; and (col. 4, lines 1-9; 17-44; 48-51; col.7, lines 55-61; col. 8, lines 41-67)
- comparing said second associated report with said order or with said associated report using a computer; and (col. 4, lines 17-44)
- wherein the determination step further depends upon whether said second associated report supports said order. (col.7, lines 55-61; col. 8, lines 41-67)

Colella teaches a method of processing “own use” prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for an own use discount or not. However, Colella does disclose

validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 15] Colella discloses the method of claim 9 further comprising the steps of:

- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; (col. 4, lines 1-9; col. 8, lines 41-67)
- entering said second associated report as data into said computer; and (col. 4, lines 1-9)
- comparing said second associated report with said order using a computer; (col. 4, lines 17-44; col. 8, lines 41-67) and
- wherein the determination step further depends upon whether said second associated report supports said order. (col.7, lines 55-61; col. 8, lines 41-67)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer

qualifies for an own use discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize “own use” pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for “own use” discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 16] Colella discloses a method for processing orders for pharmaceuticals further comprising the steps of:

- receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical (Figs. 4, 6; col. 5, lines 33-43),
- receiving a first associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; (col. 4, lines 1-9)
- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; and (col. 4, lines 1-9; col. 8, lines 41-67)

- analyzing said first associated report and said second associated report to determine an extent to which they support said order; and (col. 4, lines 17-44; col. 6, lines 65-col. 7, line 32; col. 8, lines 41-44)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination of whether the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 17] Colella discloses a method of claim 16 further comprising the step of placing said order with a pharmaceutical seller based upon certain criteria (col. 5, lines 33-43; col. 6, line 65-col. 7, line 20;col. 8, lines 59-67), but does not disclose applying an own use discount in response to said status determination identifying the buyer as qualified for said "own use" discount. Gardner discloses a method for detecting fraud

and ensuring that purchasing agencies qualify for and properly receive “own use” pharmaceutical discounts on drug orders. (pg. 74, par. 2,4) At the time of the Applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to verify qualifications for pharmaceutical “own use” discounts and to apply the discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 18] Colella discloses a method further comprising the step of sending either said first associated report or said second associated report to said pharmaceutical seller. (col. 4, lines 1-9; col. 5, lines 33-43)

[claim 19] Colella discloses a method further comprising the step of allowing said pharmaceutical seller to have access to either said first associated report or said second associated report. (col. 4, lines 1-9; col. 5, lines 33-43)

[claim 20] Colella discloses a method further comprising the step of placing said order with a pharmaceutical seller based upon certain criteria (col. 5, lines 33-43; col. 6, line 65-col. 7, line 20;col. 8, lines 59-67), but does not disclose applying an own use discount in response to said status determination identifying the buyer as qualified for said "own use" discount. Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly receive “own use” pharmaceutical

discounts on drug orders. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to verify qualifications for pharmaceutical "own use" discounts and to apply the discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 21] Colella discloses the method of claim 20 further comprising the step of sending said associated report to said pharmaceutical seller. (col. 4, lines 1-9; col. 5, lines 33-43)

[claim 22] Colella discloses the method of claim 20 further comprising the step of allowing said pharmaceutical seller to have access to said associated report. (col. 4, lines 1-9; col. 5, lines 33-43)

[claim 23] Colella discloses a method further comprising the steps of generating a status report and sending said status report to said pharmaceutical seller. (col. 4, lines 1-9; col. 5, lines 33-43; col. 7, lines 55-61)

[claim 25] Colella discloses the method of claim 20 further comprising the step of arranging for said pharmaceutical seller to directly ship an appropriate quantity of said type of pharmaceutical directly (col. 5, lines 33-43; col. 8, line 59-67) to one of an entity comprised of at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical; or at least one nursing home having at least one patient needing

said type of pharmaceutical. (col. 3, line 29-col. 4, line 26; Figure 1A)

[claim 27] Colella discloses the method of claim 1 further comprising the step of generating a status report. (col. 7, lines 55-61)

[claim 28] Colella and Gardner teach the method of claim 1 as explained in the rejection of claim 1. Colella further discloses a method comprising adjusting the order so that the order is supported by said associated report, in response to a comparison resulting in the determination status order was not previously acceptable (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67). The order amount is reduced/deducted if it is not compliant with order standards so that the order can go through.

[claim 29] Colella discloses the method of claim 28 wherein the step of adjusting said order comprises calculating a stand by requirement for said buyer. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67).

[claim 30] Colella discloses a pharmaceutical order auditing system, said pharmaceutical order auditing system comprising:

- a first input for receiving pharmaceutical order data, said order data comprising a type of pharmaceutical, a quantity of said type of pharmaceutical, and a buyer requesting said quantity of said type of pharmaceutical; (Figure 1; col. 3, lines 29-67; col. 4, lines 8-26; col. 5, lines 33-43)

- a second input for receiving audit data (i.e. receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer (Figure 1B; col. 4, lines 1-9))
- a processor (Figure 1A; col. 3, lines 29-60; col. 4, lines 4, lines 45-54)
- software that is executed on said processor (col. 3, lines 29-39) configured to compare said order data with said audit data (i.e. comparing said order with said associated report; and (col. 4, lines 1-9; 17-44; 48-51)
- an output for communicating a status determination to a user. (Figs. 1, 4-6;col. 6, lines 31-34, e.g. screen; interfaces; col. 7, lines 55-61—printer)

Colella teaches a system of processing prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not (i.e. if the user is one of the qualified categories of buyers). However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize “own use” pharmaceutical discounts. (pg. 74, par. 2, bullet 6 and par. 4) At the time of the Applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for “own use” discounts and to apply a discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 32] Colella discloses the pharmaceutical order auditing system of claim 30 wherein said audit data is gathered from a medication administration record for each of said patients in the at least one nursing home (Figure 1;col. 4, lines 1-26)

[claim 33] Colella discloses a pharmaceutical order auditing system including a plurality of input devices (e.g. a third input device) for receiving additional audit data. (col. 3, lines 29-67) (e.g. receiving associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer--col. 4, lines 1-9; col. 8, lines 41-67) and wherein the determination step further depends upon the additional audit information (i.e. associated report supports said order) (col.7, lines 55-61; col. 8, lines 41-67)

However, Colella does not expressly disclose determining whether if the buyer qualifies for an “own use” discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize “own use” pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for “own use” discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation

federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 34] Colella discloses the pharmaceutical order auditing system of claim 33 wherein said additional audit data is gathered from a report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer. (col. 4, lines 1-9; col. 8, lines 41-67 --i.e. a physicians order sheet for each of said patients or medication administration record for each of said patients)

[claim 35] Colella discloses the pharmaceutical order auditing system of claim 30 wherein said audit data comprises a type of pharmaceutical, an amount of said type of pharmaceutical requested by each of said retail pharmacies (col. 4, lines 1-26; col. 4, lines 33-43; col. 6, lines 65-col. 7, lines 20) and each of said nursing homes requesting each of said amounts from each of said retail pharmacies (col. 5, lines 33-56). Colella further discloses a system wherein compare said order data with said audit data (i.e. comparing said order with said associated report; and (col. 4, lines 17-44)

However, Colella does not expressly disclose making a status determination if the buyer qualifies for the “own use” discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize “own use” pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant’s invention, it would have been obvious to one of

ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts and to apply a discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 36] Colella discloses the pharmaceutical order auditing system of claim 35 including a plurality of input devices (e.g. a third input device) for receiving additional audit data. (col. 3, lines 29-67) (e.g. receiving associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer--col. 4, lines 1-9; col. 8, lines 41-67) and wherein the determination step further depends upon the additional audit information (i.e. associated report supports said order) (col.7, lines 55-61; col. 8, lines 41-67)

However, Colella does not expressly disclose determining whether if the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by

Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 37] Colella discloses a system wherein order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, (col. 4, lines 1-26--e.g. variety, quantity, delivered to each patient—associated with each ddm location; col. 5, lines 33-43) and wherein said audit data further comprises each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals. (Figure 1B; col. 4, lines 3-9)

Colella further discloses a method/system wherein the software is further configured to compare said patient identifiers in said additional audit data with patient data/identifiers in order data(col. 4, lines 5-26), said status determination further depending upon whether said patient identifier comparison results in a sufficient number of matches between said audit data patient identifiers and said order data patient identifiers. (i.e. verification to determine whether quantities are consistent with the patients' level of consumption (e.g. prescription) are performed—col. 6, lines 65-col. 7, lines 27; col. 8, lines 41-65)

[claim 45] Colella discloses the pharmaceutical order auditing system of claim 30 wherein said output is communicated to said user as a status report. (col. 7, lines 55-61)

[claim 46] Colella discloses the pharmaceutical order auditing system of claim 30

including a plurality of input devices (e.g. a third input device) for receiving additional audit data. (col. 3, lines 29-67) (e.g. receiving associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer--col. 4, lines 1-9; col. 8, lines 41-67) and wherein the determination step further depends upon the additional audit information (i.e. associated report supports said order) (col.7, lines 55-61; col. 8, lines 41-67)

However, Colella does not expressly disclose determining whether if the buyer qualifies for an “own use” discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize “own use” pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for “own use” discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 47] Colella discloses the pharmaceutical order auditing system of claim 30 wherein said software is further configured to allow for a tolerance in making said status determination. (col. 7, lines 55-61; col. 9, lines 9-53—e.g. optional override features in the reporting and review functions)

[claim 48] Colella discloses a system wherein the software may adjust the order so that there is a sufficient match between the adjusted order and the audit data and the requirements in a status determination can be met. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67—see 112, 2nd rejection). The order amount is reduced/deducted if it is not compliant with order standards so that the order can go through.

[claim 49] Colella discloses the pharmaceutical order auditing system of claim 48 wherein said software is configured to calculate a stand by requirement for said buyer if said order needs adjustment. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67).

[claim 62] Colella discloses a computer-implemented method for processing orders for pharmaceuticals, said method comprising the steps of:

- receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical; (Figs. 4, 6; col. 5, lines 33-43) wherein the said buyer includes an entity comprised of at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical. (col. 3, line 29-col. 4, line 26; col. 5, lines 33-43; Figure 1A) (Examiner interprets language to mean only one of the listed options need to be included)
- receiving information summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; (col. 4, lines 1-9)

- comparing said order with said information; and (col. 4, lines 17-44)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claims 63-64] Colella discloses the pharmaceutical order auditing method wherein said information comprises information from at least one of a physicians order sheet or medication administration record. (col. 4, lines 1-9; col. 8, lines 41-67; Figures 5-6))

[claim 65] Colella discloses a method wherein said buyer comprises at least one retail pharmacy (Figure 1A; col. 3, line 29-col. 4, line 26; col. 5, lines 33-43)

[claim 66] Colella teaches a method wherein said buyer comprises said entity. (Figure

1A ; col. 3, line 29-col. 4, line 26; col. 5, lines 33-43)

[claim 68] Colella and Gardner teach the method of claim 63 as explained in the rejection of claim 63. Furthermore, Colella discloses a method further comprising adjusting the order to an appropriate sub quantity if so that the requirements in a status determination can be met. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67—see 112, 2nd rejection). The order amount is reduced/deducted if it is not compliant with order standards so that the order can go through.

[claim 69] Colella discloses a pharmaceutical order auditing system, said pharmaceutical order auditing system comprising:

- a computer for receiving and processing data related to a pharmaceutical order; (Figure 1; col. 3, lines 29-67; col. 4, lines 8-26; col. 5, lines 33-43), said audit being based upon ate least two types of audit data that are compared to said order performing comparisons between orders and related data; (Figure 1B; col. 4, lines 17-44—e.g. type and quantity take by patients)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, line 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize “own use” pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for “own use” discounts and to apply a discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 70,74] Colella discloses a system further comprising:

- a second computer in communication with said computer via a network, said second computer being configured to provide said computer with information that summarizes at least one "own use" pharmaceutical need of at least one patient who is supplied with pharmaceuticals by the buyer, (Figures 1A-1B; col. 3, line 9- col. 4, lines 26) and
- wherein the computer is further configured to perform an audit by comparing said order with said information (i.e. performing comparisons between orders and related data; Figure 1B; col. 4, lines 17-44))

Colella teaches a method of processing prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for an “own use” discount or not. However, Colella does disclose validation/review steps for

verifying the request for pharmaceuticals. (col. 7, line 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts and to apply a discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

Claim 70 further recites that the second computer is configured to provide said (first) computer with a retail pharmacy listing. Colella and Gardner in combination disclose a computerized auditing process as explained do not expressly disclose providing retail pharmacy listing. However, Gardner does disclose that an important audit check to consider to when validating the application of "own use" discounts is having background information practices of pharmacies (e.g. accounting practices, hiring practices, inventory data, etc) (page 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one ordinary skill in the art to modify the system/method of Colella in combination to provide a retail pharmacy listing. One would have been motivated to include this feature to avoid the legal consequences and ramifications of improper or illegal transactions under the applicable statutes and codes, as suggested by Gardner. (page 74, par. 2)

[claim 71] Colella teaches a system wherein the nursing home information comprises information from a physician order sheet (POS) corresponding to said at least one patient or information from a medication administration record (MAR) corresponding to said at least one patient. (col. 4, lines 1-9; col. 8, lines 41-67; Figures 5-6)

[claim 72] Colella discloses a system wherein the buyer is at least one retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility, or at least one hospital; at least one nursing home; or at least one long term health care facility. (Figure 1A; col. 3, line 29-col. 4, line 26; col. 5, lines 33-43)

[claim 73] Colella discloses a system wherein the computer is further configured to adjust the order to an appropriate sub quantity in response to the status determinations so that the requirements in a status determination can be met. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67—see 112, 2nd rejection). The order amount is reduced/deducted if it is not compliant with order standards so that the order can go through.

[claim 75] The limitations of claim 75 are substantially similar to claims 69 and 73. As such, claim 75 is rejected for the reasons provided in the rejections of claim 69 and 73,

and incorporated herein.

[claim 76] The limitations of claim 76 are addressed by the rejection of claims 1 and 28, and incorporated herein.

[claim 77] Colella discloses calculating a stand by requirement for a buyer for a pharmaceutical order. (col. 7, lines 7-11—e.g. adjusting order for holdover quantity)

[claim 78] Colella discloses the pharmaceutical order auditing method of claim 62 wherein said data is gathered from a report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer or a physicians order sheet for each of said patients or medication administration record for each of said patients. (col. 4, lines 1-9; col. 8, lines 41-67)

[claims 79-80] Colella discloses the pharmaceutical order auditing method of claim 16 wherein said second associated report is gathered from a nursing home or hospital summarizing the "own use" pharmaceutical needs of at least one patient (including a physicians order sheet for each of said patients or medication administration record for each of said patients) (col. 4, lines 1-9; col. 8, lines 41-67)

Claim 70 has been amended to recite that the information includes the second a retail pharmacy listing. Colella and Gardner in combination disclose a computerized auditing process as explained do not expressly disclose providing retail pharmacy listing. However, Gardner does disclose that an important audit check to consider to

when validating the application of "own use" discounts is having background information practices of pharmacies (e.g. accounting practices, hiring practices, inventory data, etc) (page 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one ordinary skill in the art to modify the system/method of Colella in combination to provide a retail pharmacy listing from the pharmacy. One would have been motivated to include this feature to avoid the legal consequences and ramifications of improper or illegal transactions under the applicable statutes and codes, as suggested by Gardner. (page 74, par. 2)

9. Claims 2-8,11,14, and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colella et al (USPN 6,003,006) and Gardner ("Pharmaceutical Scam: Use Audit to Detect 'Pyramid Cube Scheme'") as applied to claims 1 and 30, and in further view of Spurgeon (5,890,129)

[claim 2] Colella teaches method wherein order data may be transmitted over a network (Colella: col. 5, lines 33-43; Fig. 4, 6), but does not expressly disclose that the network includes the Internet. Spurgeon discloses a method wherein medical data is transmitted over a plurality of networks including the Internet. (Figure 1; col. 5, lines 56-65) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Colella and Gardner in combination to transmit information over the Internet. One would have been motivated to include this feature to facilitate the exchange of clinical and business information among users with within an existing environment of disparate hardware and software systems, as suggested by Spurgeon. (col. 3, lines 1-5)

[claim 3] Colella discloses a method wherein the step of receiving said associated report further comprises receiving said report as at least one computer file (i.e. in computer readable format), and wherein the comparison step is performed by a software program executed (col. 3, lines 29-39) on said computer (col. 4, lines 1-9; 17-44; 48-51)

[claim 4] Colella and Gardner in combination disclose the method of claim 3, as explained in the rejection of claim 3, but do not expressly disclose a step of converting a file format to be readable by a given software program. Spurgeon discloses a system comprising a translator that automatically translates/converts data files so that they are compliant with destination storage formats and programs. (col. 7, lines 8-21) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to further modify the system/method of Colella and Gardner in combination with the teaching of Spurgeon to include a formation conversion feature. As suggested by Spurgeon, one would have been motivated to include this feature to minimize programming costs while facilitating the exchange of information. (col. 7, lines 22-26)

[claim 5] Colella teaches a method further comprising the step of entering said associated report as data into said computer (col. 4, lines 1-9) and wherein the comparison step is performed by a software program executed (col. 3, lines 29-39) on said computer (col. 4, lines 1-9; 17-44; 48-51)

[claim 6] Colella discloses the method of claim 2 further comprising the steps of:

- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer, said second associated report being received as at least one computer file; and (col. 4, lines 1-9; 17-44; 48-51; col.7, lines 55-61; col. 8, lines 41-67)
- comparing said second associated report with said order or with said associated report using a computer; and (col. 4, lines 17-44)
- wherein the determination step further depends upon whether said second associated report supports said order. (col.7, lines 55-61; col. 8, lines 41-67)

Colella teaches a method of processing “own use” prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize “own use” pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for “own use” discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 7] Colella and Gardner in combination disclose the method of claim 6,

wherein the comparing step between the said second associated report and said order is performed by a software program (col. 3, lines 29-39) executed on said computer. (col. 4, lines 1-9; 17-44; 48-51). However, Colella and Gardner do not expressly disclose a step of converting a file format to be readable by a given software program. Spurgeon discloses a system comprising a translator that automatically translates/converts data files so that they are compliant with destination storage formats and programs. (col. 7, lines 8-21) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to further modify the system/method of Colella and Gardner in combination with the teaching of Spurgeon to include a formation conversion feature. As suggested by Spurgeon, one would have been motivated to include this feature to minimize programming costs while facilitating the exchange of information. (col. 7, lines 22-26)

[claim 8] Colella discloses the method of claim 2 further comprising the steps of:

- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; (col. 4, lines 1-9; col. 8, lines 41-67)
- entering said second associated report as data into said computer; and (col. 4, lines 1-9)
- comparing said second associated report with said order or with said associated report using a computer; and (col. 4, lines 17-44)
- wherein the determination step further depends upon whether said second

associated report supports said order. (col.7, lines 55-61; col. 8, lines 41-67)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 11] Colella and Gardner disclose the method of claim 10, as explained in the method of claim 10. However, Colella and Gardner do not expressly disclose a step of converting a file format to be readable by a given software program. Spurgeon discloses a system comprising a translator that automatically translates/converts data files so that they are compliant with destination storage formats and programs. (col. 7, lines 8-21) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to further modify the system/method of Colella and Gardner in

combination with the teaching of Spurgeon to include a formation conversion feature. As suggested by Spurgeon, one would have been motivated to include this feature to minimize programming costs while facilitating the exchange of information. (col. 7, lines 22-26)

[claim 14] Colella and Gardner in combination disclose the method of claim 13, wherein the comparing step between the said second associated report and said order is performed by a software program (col. 3, lines 29-39) executed on said computer. (col. 4, lines 1-9; 17-44; 48-51). However, Colella and Gardner do not expressly disclose a step of converting a file format to be readable by a given software program. Spurgeon discloses a system comprising a translator that automatically translates/converts data files so that they are compliant with destination storage formats and programs. (col. 7, lines 8-21) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to further modify the system/method of Colella and Gardner in combination with the teaching of Spurgeon to include a formation conversion feature. As suggested by Spurgeon, one would have been motivated to include this feature to minimize programming costs while facilitating the exchange of information. (col. 7, lines 22-26)

[claim 38] Colella and Gardner in combination teach the pharmaceutical order auditing system substantially as recited in claim 35 as explained in the rejection of claim 35. Colella further discloses that the information transmitted in the system may be in one of several formats (col. 4, lines 48-51). However, Colella and Gardner do not expressly disclose a system further comprising a converter configured to convert (audit)

data to a common format. Spurgeon discloses a system further comprising a translator/converter which translates/converts data from different sources into a common format (col. 6, line 56-60; col. 7, lines 8-16). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Colella and Gardner in combination to include a converter or translator to convert data to a specific format. As suggested by Spurgeon, one would have been motivated to include this feature to accommodate data from a plurality of sources, while still permitting each data provider to use the proprietary system of their choice (col. 4, lines 56-64)

[claim 39] Colella discloses a system wherein said audit data further comprises medication administration records for each of said patients in each of said nursing homes. (Figure 1B; col. 4, lines 3-9)

[claim 40] Colella discloses the pharmaceutical order auditing system of claim 38 including a plurality of input devices (e.g. a third input device) for receiving additional audit data. (col. 3, lines 29-67) (e.g. receiving associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer--col. 4, lines 1-9; col. 8, lines 41-67) and wherein the determination step further depends upon the additional audit information (i.e. associated report supports said order) (col.7, lines 55-61; col. 8, lines 41-67)

However, Colella does not expressly disclose determining whether if the buyer qualifies for an "own use" discount or not. However, Colella does disclose

validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize “own use” pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for “own use” discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 41] Colella discloses the pharmaceutical order auditing system of claim 40 wherein said additional audit data is gathered from a report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer. (col. 4, lines 1-9; col. 8, lines 41-67 --i.e. a physicians order sheet for each of said patients or medication administration record for each of said patients)

[claim 42] Colella and Gardner in combination teach the pharmaceutical order auditing system substantially as recited in claim 40 as explained in the rejection of claim 40. Colella further discloses that the information transmitted in the system may be in one of several formats (col. 4, lines 48-51). However, Colella and Gardner do not expressly disclose a system further comprising a converter configured to convert (audit) data to a

common format. Spurgeon discloses a system further comprising a translator/converter which translates/converts data from different sources into a common format (col. 6, line 56-60; col. 7, lines 8-16). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Colella and Gardner in combination to include a converter or translator to convert data to a specific format. As suggested by Spurgeon, one would have been motivated to include this feature to accommodate data from a plurality of sources, while still permitting each data provider to use the proprietary system of their choice (col. 4, lines 56-64)

[claim 43] Colella discloses the system of claim 40 wherein order data further comprises a plurality of identifiers each of said patients needing said quantity of said type of pharmaceutical, (Figure 6; col. 5, lines 33-43), wherein said additional audit data further comprises a plurality of each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals. (Figure 1B; col. 4, lines 1-26)

Colella also discloses a method/system wherein the software is further configured to compare said patient identifiers in said audit data with patient data in said order (col. 4, lines 5-26), status determination further depending upon whether said patient identifier comparison results in a sufficient number of matches between said audit data patient identifiers and said order data patient identifiers. (i.e. verification to determine whether quantities are consistent with the patients' level of consumption (e.g. prescription) are performed—col. 6, lines 65-col. 7, lines 27; col. 8, lines 41-65)

[claim 44] Colella discloses the system of claim 38 wherein order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, (Figure 6; col. 4, lines 5-26) and wherein said audit data further comprises each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals. (Figure 1B; col. 4, lines 1-26)

Colella also discloses a method/system wherein the software is further configured to compare said patient identifiers in said audit data with patient data in said order (col. 4, lines 5-26), status determination further depending upon whether said patient identifier comparison results in a sufficient number of matches between said audit data patient identifiers and said order data patient identifiers. (i.e. verification to determine whether quantities are consistent with the patients' level of consumption (e.g. prescription) are performed—col. 6, lines 65-col. 7, lines 27; col. 8, lines 41-65)

(10) Response to Argument

(A) Applicant argues that claim 69 should not be rejected for use of "single means" language, because it does not recite the term "computer" should not be interpreted as a "means plus function" limitation.

As explained in the claim rejection, claim 69 recites "[a] ***system*** for determining whether a buyer qualifies for an "own use discount" ***comprising: a computer***

configured to perform an "own use" discount audit to determine whether an order qualifies for an "own use" discount." (A system comprising one component, which performs all functions, i.e. a single means claim.) The current claim does not expressly recite "means for" language. However, in *Fiers v. Revel,* (CAFC) 25 USPQ2d 1601, 1606 (1/19/1993), the CAFC affirmed a rejection under 35 USC 112 of a claim reciting a single element that did not literally use "means-plus-function" language.

Instant claim 69 is drawn to any "computer", regardless of construct, that performs the function recited. This parallels the fact situation in *Fiers* wherein "a DNA" and a result was recited. The CAFC stated in *Fiers* at 1606 "Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived". See also *Ex parte Maizel,* (BdPatApp&Int) 27 USPQ2d 1662, 1665 and *Ex parte Kung,* (BdPatApp&Int) 17 USPQ2d 1545, 1547 (1/30/1989) where the claims at issue were rejected for being analogous to single *means* claims even though "means" was not literally used.

The Examiner notes the Appellant's arguments against the comparison of the current claim language that in the *Fiers* case. However, it is respectfully submitted that the recitation of a "computer" does not clarify which component(s) are present (i.e. the processor, the memory, input and output, and/or software). In other words, the claim language recites a system "that achieve[s] a result without defining what means will do so…" As such, the rejection of claim 69, is proper and should be maintained.

(B) Appellant argues that the term "sufficient" is not a relative term that renders claims 37, 43, and 44 indefinite.

In response, the Examiner respectfully disagrees that the Appellants assertion. The determination of whether “sufficient “ criteria have been met is vague and subjective.

In particular , the term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Therefore, the rejection of claims 37, and 43-44 under 35 USC 112, 2nd is proper and should be maintained.

(C) Appellant argues that the rejection of claims 69-74 under 35 USC 112, 2nd is improper.

In response, the preamble of claim 69 recites a system, however the body of the claim recites only one element: a computer. Subsequent claim describe 70 recites a second computer "in communication with *said computer* via a network.....wherein *the computer* is further configured to perform said “own use” audit…”

The claim limitations or recitations, particularly of claim in claim 70, render the functions of the computer in claim 69 unclear. In particular, it is unclear whether the single computer recited in claim 69 is now meant to perform all the functions of the “the computer” or “said computer” or if “the computer”/ “said computer” refers to the second computer.

Dependent claims 70-74 inherit the deficiencies of the independent claim 69 through dependency and are therefore also rejected.

(D) Applicant argues that the references fail to render obvious the method of claim 1 and render obvious the concept of performing an audit on a pharmaceutical order.

In response the Examiner respectfully disagrees with applicant's interpretation of the prior art. Both the Colella and Gardner disclose performing audit and tracking pharmaceutical orders. Colella discloses the review and ability to adjust a drug purchase order (col. 7, lines 35-54; col. 8, lines 41-67) in a healthcare facility (e.g. hospital; nursing home) (col. 2, lines 44-52) Furthermore, the Gardner reference as a whole, discloses "own use" pharmaceutical discounts, and the significance of performing audits (see pg. 74, par. 2, 4 in particular).

As stated in the rejection of claim 1, at the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

(E) Appellant argues that the prior art does not render obvious claim 62 because the prior art does not disclose the concept of determining an "own use" discount status for a proposed "own use" purchase.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As explained in the rejection of claim 62, Colella teaches a method of processing "own use" prescription orders including receiving and tracking drug information, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals (i.e. a "proposed order"). (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation

federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4).

(F) Appellant argues that the prior art does not disclose the limitations of claim 65 and 66.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., distinction between closed pharmacies and retail pharmacies) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Moreover, any requirements defining how each party may participate is defined by federal regulation and court rulings and is not a function of the claimed invention (see Gardner: page 74, par. 2)

Colella discloses a method wherein said buyer comprises at least one retail pharmacy and wherein said buyer comprises said entity. (Figure 1A; col. 3, line 29-col. 4, line 26; col. 5, lines 33-43).

(G) The Appellant argues that the prior art fails to render obvious the limitations of claim 30.

In response, the Examiner respectfully disagrees with the Appellants interpretation of the prior art. Colella was relied upon to disclose the hardware and some functionality of a system for processing prescription orders as a explained in

rejection of claim 30, but does not expressly disclose making a status determination if the buyer qualifies for discount or not (i.e. if the user is one of the qualified categories of buyers). However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 2, bullet 6 and par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts and to apply a discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

(H) Appellant argues that the Colella and Gardner references do not render obvious the limitations of claim 76. In particular, the prior art fails to disclose determining whether an entity is entitled to an own use discount and adjusting an order based up an evidence report.

Again, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

Therefore, Colella and Gardner in combination were relied upon to disclose the determination of "own use" eligibility.

Furthermore, Colella discloses a method comprising adjusting the order so that the order is supported by said associated report, in response to a comparison resulting in the determination status order was not previously acceptable (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67). The order amount is reduced/deducted if it is not compliant with order standards so that the order can go through.

(I) Appellant argues that the prior art fails to meet the limitations of claim 75 because it

does not disclose adjusting the order to a subquantity as a part of the auditing process.

In response, Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

Therefore, Colella and Gardner in combination were relied upon to disclose the determination of "own use" eligibility.

Furthermore, Colella discloses a method comprising adjusting the order so that the order is supported by said associated report, in response to a comparison resulting in the determination status order was not previously acceptable (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67). The order amount is reduced/deducted if it is not compliant with order standards so that the order can go through.

It is respectfully submitted that any remaining quantity is a “subquantity" by definition.

(J) Appellant argues that the limitations of claims 28,48,68, and 73 are not rendered are not rendered obvious by the prior art.

In response, the Appellant's arguments regarding claims 28,48,68, and 73 are addressed by the Examiner's arguments regarding claims 75 and 76, and incorporated herein.

(K) Appellant argues that the limitations of claims 29,49, and 77 have not been addressed by the prior art, be cause the prior art does not disclose calculating a standby requirement.

In response, Colella discloses calculating a stand by requirement for a buyer for a pharmaceutical order. (col. 7, lines 7-11—e.g. adjusting order for holdover quantity). Appellant argues that the applied citation from Colella is not same as the applicant’s intended “stand by amount”.

However, in response to applicant's argument that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies (i.e., the purpose and function of the standby quantity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(L) Appellant argues that the prior art fails to disclose the limitations of claim 16 and claim 69 because it does not render obvious the use of two reports to assess whether an order eligible for an "own use discount."

In response, Colella discloses the use of multiple reports in the processing, tracking, and ordering of pharmaceuticals as explained in rejection of claim 16. Moreover, Colella discloses that the order goes through an auditing/verification process, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly receive "own use" pharmaceutical discounts on drug orders. (pg. 74, par. 2,4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to verify qualifications for pharmaceutical "own use" discounts and to apply the discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

It is respectfully submitted that the claim language does not clarify or state which documents are used or what information must be provided, only that multiple reports must be provided to validate the order.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/R. L. P./

Examiner, Art Unit 3626

/C Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626

Vincent Millin /VM/

Appeals Conference Specialist

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Wynn W. Coggins/

Director, TC 3600

Conferees:

/C. G./

Supervisory Patent Examiner, Art Unit 3626

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